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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,453	07/29/2003	Rossella Musa	241019US0DIV	4847
22850	7590	11/16/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			OH, SIMON J	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/628,453	<b>Applicant(s)</b> MUSA ET AL.	
	<b>Examiner</b> Simon J. Oh	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14, 15, 18-25, 28, 29, 31, 32 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 18-25, 28, 29, 31, 32 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/926,105.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1618

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's request for continued examination, received on 19 October 2005.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 11, 26, 27, 30, 33 and 35 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth and Sarlikiotis *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 14, 15, 18-25, 28, 29, 31, 32 and 36-38 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth and Sarlikiotis *et al.* is maintained.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth (U.S. Patent No. 6,153,224) and Sarlikiotis *et al.* (U.S. Patent No. 6,284,287)

The Staniforth patent teaches a process for treating inhaler carrier particles in order to allow a higher respirable fraction of the active substance (See Abstract). The carrier particles are preferably lactose particles, such as alpha lactose monohydrate (See Column 4, Lines 35-41; and Example 1, Column 10, Line 67). The preferred range of particle sizes lie in the range of 60

Art Unit: 1618

microns to 180 microns; Example 1 uses particles in the range of 90 microns to 125 microns (See Column 4, Lines 42-57; and Column 11, Lines 3-22). The carrier particles include additives, which promote the release of the active substance particles from the carrier particles upon actuation of the inhaler (See Column 3, Lines 3-6). Suitable additive materials include stearic acid, magnesium stearate, and sodium stearyl fumarate (See Column 5, Lines 36-55). In most cases, the amount of additives does not exceed more than 2% by weight (See Column 4, Lines 6-14). The mass median diameter of the active substance particles is preferably less than 5 microns (See Column 7, Lines 36-43). Suitable active substances disclosed by the patent include salmeterol, salbutamol, ipratropium bromide (See Column 7, Lines 44-64), and beclomethasone dipropionate (See Example 1, Column 11, Line 43). The patent also discusses the treatment of the carrier particles in order to alleviate surface irregularities. In the course of the treatment, asperities of the carrier particles are removed as smaller grains and attach themselves to high surface energy sites, without significantly changing the particle size of the carrier particles themselves (See Column 8, Lines 51-65; Column 9, Lines 6-37; and Column 10, Lines 1-27). The patent states that the carrier particles are treated with the addition of the additives, and may be mixed for 0.1 hours to 0.5 hours (6 to 36 minutes), using a tumbling blender, such as a Turbula Mixer (See Column 8, Lines 47-50; and Example 1, Column 11, Lines 23-28). Alternatively, the carrier may be treated alone, before the addition of any additive; or with the addition of both the additive and the active substance (See Column 8, Line 66 to Column 9, Line 5). The treatment may also be carried out in a mill, such as a ball mill, for a period of time ranging from 0.25 hours (15 minutes) to 6 hours (360 minutes) (See Column 9, Lines 38-67).

Art Unit: 1618

Staniforth does not give a specific example where the treatment of the carrier particles is carried out for 30 minutes, nor does it teach the use of a sigma blade mixer, running at a speed between 100 to 300 rpm.

The Sarlikiotis *et al.* patent teaches a formulation for use in an inhaler, which comprises active substance particles coating carrier particles. Substances suitable as carrier particles include lactose, as well as its derivatives (See Column 4, Lines 14-16). The active substance used should have a particle size of 0.01 microns to 10 microns in order to ensure sufficient attraction to the carrier particles (See Column 2, Lines 61-64). The list of suitable active substances include ipratropium bromide, oxytropium bromide, beclomethasone, budesonide, flunisolide, formoterol, salbutamol, salmeterol, and terbutalin; esters of the drugs may be used as well, including dipropionate (See Column 3, Lines 24-65). Preparation of the formulation is carried out in a mixer, such as a tumble mixer, a rotary mixer, or a high-speed mixer; the Turbula Mixer is given as an example of a tumble mixer (See Column 4, Lines 32-37). Both the active substance and the carrier particles are mixed in the mixer until the carrier particles are coated with the active substance, with “the fine fraction gradually disappearing and round, coated particles resulting” (See Column 4, Lines 38-41). Examples are given where the preparation is carried out in a mixer, for 30 minutes (See Examples 1 and 2).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Staniforth in view of Sarlikiotis *et al.* Sarlikiotis *et al.* teach a mixing time of 30 minutes, as well as an expanded list of suitable active substances. Furthermore, it would be obvious that the mixing process described in Sarlikiotis *et al.* would modify the surface properties of the carrier particles, as described in Staniforth. It is the opinion of the examiner

Art Unit: 1618

that as the prior art has disclosed the same process as instantly claimed in the present application, adjustment of that process to obtain a powder formulation having of Carr's index of less than 25 would be within the purview of one of ordinary skill in the art. Thus, the invention, as a whole, is *prima facie* obvious.

### ***Double Patenting***

The rejection of Claims 11, 26, 27, 30, 33 and 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S. Patent No. 6,641,844 is rendered moot with the cancellation of those claims.

The rejection of Claims 14, 15, 18-25, 28, 29, 31, 32 and 36-39 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S. Patent No. 6,641,844 is maintained.

Claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S. Patent No. 6,641,844. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to processes for the modification of surface properties of particles for use as carrier particles for the pulmonary administration of micronized drugs by means of dry powder inhalers. In certain embodiments of both processes, the carrier particles consist of  $\alpha$ -lactose monohydrate. In other embodiments of both processes, the starting diameter of the carrier particles lies between 90 and 150  $\mu\text{m}$ . Both processes also use the same broad group of active ingredients and the same broad group of lubricants.

***Response to Arguments***

Applicant's arguments filed 30 August 2005 have been fully considered but they are not persuasive.

The examiner disagrees with the applicant's interpretation of the prior art. Regarding the applicant's quote of Column 2, Lines 13-16 of the Staniforth reference, the particles referred to are not the fine carrier fraction described in the applicant's instant application. Rather, they are the starting carrier particles. What the applicant refers to as the fine carrier fraction corresponds to the asperities and grains described in Staniforth (See Column 8, Lines 51-65; and Page 3 of the final office action of 22 April 2005). Regarding the applicant's arguments of the disclosure in the Staniforth reference regarding the use of magnesium stearate, the examiner points to MPEP § 2123, where non-preferred embodiments still constitute applicable prior art. Furthermore, the prior art provides guidance as to the use of this additive, thus providing an enabling disclosure (See Column 4, Lines 6-14; and Column 5, Line 39 to Column 6, Line 5). Such an interpretation of the prior art is not sufficient to overcome the prior art rejection of record. Therefore, the claims will remain rejected under 35 U.S.C. 103.

Regarding the present rejection of the claims under the judicially created doctrine of obviousness-type double patenting, the examiner has not received any terminal disclaimer as stated by the applicant in the response dated 30 August 2005. Therefore, the double patenting rejection will also be maintained.

Art Unit: 1618

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1618

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